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Tariff Commission Notice

DEPARTMENT OF THE TREASURY
U.S. Customs Service

NOTICE

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U.S. Customs Service

(T.D. 74-126)

Radial ball bearings—Increase in duty

Presidential Proclamation No. 4279 providing for the increased rates of duty on certain radial ball bearings

DEPARTMENT OF THE TREASURY,
OFFICE OF THE COMMISSIONER OF CUSTOMS,
Washington, D.C., April 12, 1974.

The text of Presidential Proclamation No. 4279, increasing the duty on certain radial ball bearings having an outer diameter 9 mm and over but not over 100 mm is set forth below.

The proclamation in part modifies Subpart A, Part 2, of the Appendix to the Tariff Schedules by inserting, in numerical sequence, new items 923.80, 923.82, and 923.84 with increased duty rates on the ball bearings covered by these items. The modifications are effective as to articles entered, or withdrawn from warehouse, for consumption during the period commencing May 1, 1974, and terminating at the close of April 30, 1978.

(434.01)

LEONARD LEHMAN,
Assistant Commissioner,
Regulations and Rulings.

BY THE PRESIDENT OF THE UNITED STATES OF AMERICA

A PROCLAMATION

1. WHEREAS, pursuant to the authority vested in him by the Constitution and the statutes, including section 350 of the Tariff Act of 1930, as amended (19 U.S.C. 1351), and section 201 of the Trade Expansion Act of 1962 (19 U.S.C. 1821) (TEA), the President, by proclamations, including Proclamation No. 3822 of December 16, 1967 (82 Stat. 1455), proclaimed such modifications of existing duties as were found to be required or appropriate to carry out certain trade agreements into which he had entered;

2. WHEREAS among the proclaimed modifications were modifications in the rate of duty on ball bearings which are now provided for in item 680.35 of the Tariff Schedules of the United States (TSUS);

3. WHEREAS the United States Tariff Commission has submitted to me a report of its Investigation No. TEA–I–27 of July 30, 1973, under section 301(b)(1) of the TEA (19 U.S.C. 1901) and a supplemental report with respect to such investigation pursuant to my request for additional information under section 351(a)(4) of the TEA (19 U.S.C. 1981(a)(4)), on the basis of which investigation and a hearing duly held in connection therewith the said Commission has determined in part that radial ball bearings having an outside diameter of 9 mm and over but not over 100 mm, provided for in TSUS item 680.35 are, as a result in major part of concessions granted thereon under trade agreements, being imported in such increased quantities as to cause serious injury to the domestic industry producing like or directly competitive products;

4. WHEREAS section 302(a)(1) and section 351(a)(1) of the TEA (19 U.S.C. 1902(a)(1) and 19 U.S.C. 1981(a)(1)) authorize the President, upon receiving an affirmative finding of the Tariff Commission under section 301(b) of the TEA with respect to an industry, to proclaim such increase in, or imposition of, any duty or other import restriction on the articles causing or threatening to cause serious injury to such industry as he determines to be necessary to prevent or remedy serious injury to such industry;

5. WHEREAS section 302(a)(2) and section 302(a)(3), respectively, of the TEA (19 U.S.C. 1902(a)(2) and 19 U.S.C. 1902(a)(3)) authorize the President, upon receiving an affirmative finding of the Tariff Commission under section 301(b) of the TEA with respect to an industry, to provide with respect to such industry that its firms may request the Secretary of Commerce for certifications of eligibility to apply for adjustment assistance under chapter 2 of title III of the TEA (19 U.S.C. Chapter 7, Subchapter III, Part II) and that its workers may request the Secretary of Labor for certifications of eligibility to apply for adjustment assistance under chapter 3 of title III of the TEA (19 U.S.C. Chapter 7, Subchapter III, Part III); and

6. WHEREAS I have determined that the rates of duty hereinafter proclaimed are, when coupled with the adjustment assistance hereinafter provided, necessary to remedy serious injury to the industry producing radial ball bearings.

NOW, THEREFORE, I, RICHARD NIXON, President of the United States of America, acting under the authority vested in me by the Constitution and the statutes, including sections 302(a)(1), (2), (3), and (4) and 351(a)(1) of the Trade Expansion Act of 1962, and in accordance with Article XIX of the General Agreement on Tariffs and Trade (61 Stat. (pt. 5) A58; 8 UST (pt. 2) 1786), do proclaim that—

1. The tariff concessions on ball bearings for item 680.35 in Part I of Schedule XX to the Geneva (1967) Protocol to the General Agreement

on Tariffs and Trade (19 UST (pt. 2) 1530 *et seq.*) are modified in part to conform with the provisions set forth in the annex to this proclamation for such time and to such extent as provided for therein.

2. Subpart A of Part 2 of the Appendix to the Tariff Schedules of the United States is modified by the insertion, in numerical sequence, of such new items as are set forth in the annex to this proclamation.

3. The modifications in rates of duty established by paragraphs 1 and 2 shall be effective as to articles entered, or withdrawn from warehouse, for consumption during the period commencing May 1, 1974, and terminating at the close of April 30, 1978.

4. Provision is hereby made with respect to the industry producing radial ball bearings that its firms may request the Secretary of Commerce for certifications of eligibility to apply for adjustment assistance under chapter 2 of title III of the Trade Expansion Act of 1962 and that its workers may request the Secretary of Labor for certifications of eligibility to apply for adjustment assistance under chapter 3 of title III of the Trade Expansion Act of 1962.

IN WITNESS WHEREOF, I have hereunto set my hand this 29th day of March, in the year of our Lord nineteen hundred seventy-four and of the Independence of the United States of America the one hundred ninety-eighth.

RICHARD NIXON.

Annex

Item	Articles	1 Effective on or after—			
		May 1, 1974	May 1, 1976	May 1, 1977	
	Ball bearings, radial, provided for in item 680.35 of part 4J of schedule 6:				
923.80	Having an outside diameter of 9 mm and over but not over 30 mm and valued not over 60 cents each.	20% ad val.	16% ad val.	12% ad val.	No change.
923.82	Having an outside diameter of over 30 mm but not over 52 mm and valued not over 75 cents each.	---do---	---do---	---do---	Do.
923.84	Having an outside diameter of over 52 mm but not over 100 mm and valued not over $1.30 each.	3.4¢ per lb. + 15% ad val.	3.4¢ per lb. + 15% ad val.	2.6¢ per lb. + 11% ad val.	Do.

(T.D. 74-127)

Antidumping—Primary lead metal from Canada

The Secretary of the Treasury makes public a finding of dumping with respect to primary lead metal from Canada. Section 153.43, Customs Regulations, amended

DEPARTMENT OF THE TREASURY,
Washington, D.C., April 15, 1974.

TITLE 19—CUSTOMS DUTIES

CHAPTER 1—UNITED STATES CUSTOMS SERVICE

PART 153—ANTIDUMPING

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the Secretary of the Treasury responsibility for determination of sales at less than fair value. Pursuant to this authority the Secretary of the Treasury has determined that primary lead metal from Canada is being, or is likely to be, sold at less than fair value within the meaning of section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). (Published in the Federal Register of October 12, 1973 (38 F.R. 28577).)

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the United States Tariff Commission responsibility for determination of injury or likelihood of injury. The United States Tariff Commission has determined, and on January 10, 1974, it notified the Secretary of the Treasury that an industry in the United States is being, or is likely to be, injured or prevented from being established by reason of the importation of primary lead metal from Canada that is being sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. (Published in the Federal Register of January 17, 1974 (39 F.R. 2156).)

Of the four Commissioners voting, one determined that an industry in the United States is likely to be injured, and one determined that an industry in the United States is being or is likely to be injured by reason of the importation of primary lead metal from Canada sold at less than fair value, and two determined in the negative. Accordingly, for the purpose of this finding of dumping, the Tariff Commission is deemed to have determined that an industry in the United States is likely to be injured by reason of the importation of primary lead metal from Canada sold at less than fair value.

On behalf of the Secretary of the Treasury, I hereby make public this determination, which constitutes a finding of dumping with respect to primary lead metal from Canada.

Section 153.43 of the Customs Regulations is amended by adding the following to the list of findings of dumping currently in effect:

Merchandise	*Country*	*T.D.*
Primary lead metal	Canada	74–127

(Secs. 201, 407, 42 Stat. 11, as amended, 18; 19 U.S.C. 160, 173.)
(APP–2–04)

JAMES B. CLAWSON,
Acting Assistant Secretary of the Treasury.

[Published in the Federal Register April 17, 1974 (39 FR 13783)]

(T.D. 74–128)

Antidumping—Primary lead metal from Australia

The Secretary of the Treasury makes public a finding of dumping with respect to primary lead metal from Australia. Section 153.43, Customs Regulations, amended

DEPARTMENT OF THE TREASURY,
Washington, D.C., April 15, 1794.

TITLE 19—CUSTOMS DUTIES

CHAPTER 1—UNITED STATES CUSTOMS SERVICE

PART 153—ANTIDUMPING

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the Secretary of the Treasury responsibility for determination of sales at less than fair value. Pursuant to this authority the Secretary of the Treasury has determined that primary lead metal from Australia is being, or is likely to be, sold at less than fair value within the meaning of section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). (Published in the Federal Register of October 12, 1973 (38 F.R. 28308).)

Section 201(a) of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), gives the United States Tariff Commission responsibility for determination of injury or likelihood of injury. The United States Tariff Commission has determined, and on January 10, 1974, it notified the Secretary of the Treasury that an industry in the United States is being, or is likely to be, injured or prevented from being established by reason of the importation of primary lead metal from Australia that is being sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. (Published in the Federal Register of January 17, 1974 (39 FR 2156).)

Of the four Commissioners voting, one determined that an industry in the United States is likely to be injured, and one determined that an industry in the United States is being or is likely to be injured, by reason of the importation of primary lead metal from Australia sold at less than fair value, and two determined in the negative. Accordingly, for the purpose of this finding of dumping, the Tariff Commission is deemed to have determined that an industry in the United States is likely to be injured by reason of the importation of primary lead metal from Australia sold at less than fair value.

On behalf of the Secretary of the Treasury, I hereby make public this determination, which constitutes a finding of dumping with respect to primary lead metal from Australia.

Section 153.43 of the Customs Regulations is amended by adding the following to the list of findings of dumping currently in effect:

Merchandise	*Country*	*T.D.*
Primary lead metal	Australia	74–128

(Secs. 201, 407, 42 Stat. 11, as amended, 18; 19 U.S.C. 160, 173.)
(APP–2–04)

JAMES B. CLAWSON,
Acting Assistant Secretary of the Treasury.

[Published in the Federal Register April 17, 1974, (39 FR 13783)]

(T.D. 74–129)

Foreign currencies—Daily rates for countries not on quarterly list

Rates of exchange certified to the Secretary of the Treasury by the Federal Reserve Bank of New York for the Hong Kong dollar, Iran rial, Philippine peso, Singapore dollar, Thailand baht (tical)

DEPARTMENT OF THE TREASURY,
OFFICE OF THE COMMISSIONER OF CUSTOMS,
Washington, D.C., April 15, 1974.

The Federal Reserve Bank of New York, pursuant to section 522(c), Tariff Act of 1930, as amended (31 U.S.C. 372(c)), has certified buying rates in U.S. dollars for the dates and foreign currencies shown below.

These rates of exchange are published for the information and use of Customs officers and others concerned pursuant to Part 159, Subpart C, Customs Regulations (19 CFR, Part 159, Subpart C).

Hong Kong dollar:

April 1, 1974	$0.1975
April 2, 1974	.1970
April 3, 1974	.1970
April 4, 1974	.1970
April 5, 1974	.1980

Iran rial:

For the period April 1 through April 5, 1974, rate is $0.0149.

Philippine peso:

April 1, 1974	$0.1495
April 2, 1974	.1495
April 3, 1974	.1495
April 4, 1974	.1495
April 5, 1974	.1480

Singapore dollar:

April 1, 1974	$0.4040
April 2, 1974	.4100
April 3, 1974	.4120
April 4, 1974	.4110
April 5, 1974	.4110

Thailand baht (tical):

April 1, 1974	$0.0495
April 2, 1974	.0495
April 3, 1974	.0495
April 4, 1974	.0495
April 5, 1974	.0490

(LIQ-3-0:A:E)

J. D. COLEMAN
Acting Director,
Duty Assessment Division.

537-662—74——2

Decisions of the United States Customs Court

Customs Decision

(C.D. 4509)

CERTIFIED BLOOD DONOR SERVICES, INC. *v.* UNITED STATES

Nonenumerated products—Diagnostic sera

IN VITRO DIAGNOSTIC REAGENTS—FREE ENTRY

Antisera produced from rabbit blood serum by injection of antigens (human blood proteins) into rabbits, used as in vitro diagnostic reagents in immunoelectrophoresis for determining the presence of abnormal antibody proteins associated with certain forms of human cancer, known as nonoclonal gammopathies, are not "therapeutic serums", "antitoxins" or "analogous biological products" within the purview of item 437.76, TSUS. *Blank* v. *United States*, 400 F. 2d 302 (CA 5, 1968) and *United States* v. *23 7/12 Dozen Bottles, 35-Cent*

Size etc., 44 F. 2d 831, 833–34 (D.C. Conn. 1930) cited; *Sandoz Chemical Works, Inc.* v. *United States*, 43 CCPA 152 C.A.D. 623 (1956) and *Air Express International Agency, Inc., a/c Hyland Laboratories* v. *United States*, 52 Cust. Ct. 254, Abs. 68288 (1964) distinguished.

THERAPEUTIC SERUMS—COMMON MEANING

Dictionary definitions of the adjective "therapeutic" are not conclusive as to the common meaning of the provision for "therepeutic serums" in item 437.76, TSUS. However, lexicographic and other authorities describing various serums strongly indicate that "therapeutic serums" are used in vivo as immunological agents for conferring of passive immunity to certain diseases. Thus, antisera medically employed as in vitro diagnostic reagents were not "therapeutic serums" within the purview of item 437.76 TSUS.

THERAPEUTIC SERUMS—LICENSING UNDER PUBLIC HEALTH SERVICE ACT

As Congress intended item 437.76, TSUS, to "substantially correspond with the scope of the licensing requirements of the Public Health Service", it is a relevant consideration that at the time of importation of diagnostic antisera no license was issued or required by the Secretary of Health, Education, and Welfare pursuant to 42 U.S.C. § 262 in determining whether such antisera fall within the purview of item 437.76. *Tariff Classification Study Explanatory and Background Materials*, November 15, 1960, Schedule 4, part 3, p. 86; 19 CFR § 12.21 (1968).

THERAPEUTIC SERUMS—DIAGNOSTIC SERUMS—CONGRESSIONAL INTENT

The fact that in item 437.76, TSUS, Congress deemed it necessary to employ the term "diagnostic" as well as the term "therapeutic" with reference to anatomical parts indicates that Congress understood the two terms to mean something different. Moreover, when Congress intended to include in item 437.76 articles used for diagnostic purposes, it left no doubt concerning its intent. Hence, by employing only the term "therapeutic" with reference to serums, Congress clearly manifested an intent that diagnostic serums not be included as well.

"THERAPEUTIC"—LEGISLATIVE RATIFCATION OF JUDICIAL CONSTRUCTION

Legislative ratification or approval of judicial construction of the term "therapeutic" in item 437.76, TSUS, could not be assumed in the present case where the Customs Court had construed the same term under paragraph 1610 of the Tariff Act of 1930, but where the latter paragraph was worded somewhat differently than item 437.76.

ANTITOXINS—IN VITRO DIAGNOSTIC ANTISERA

An antitoxin is produced in an animal by the injection of an antigenic stimulus in the form of a toxin or toxoid, and is used in vivo to inoculate individuals to neutralize or counteract the specific type of toxin injected into the animal. The imported diagnostic antisera do not fall within the foregoing concept of an antitoxin. The antigens with which rabbits were inoculated to produce the antisera were

not in the form of a toxin or toxoid, and consequently the antibodies produced in the animal's blood were not antitoxic in nature. Moreover, the diagnostic antisera were not used in vivo to neutralize or counteract a toxin.

ANALOGOUS BIOLOGICAL PRODUCTS—DIAGNOSTIC ANTISERA

The fact that the diagnostic antisera were produced from the blood of animals (rabbits) inoculated with certain antigens (which produce antibodies) is insufficient to constitute in vitro diagnostic aids for cancer as analogous to therapeutic serums and antitoxins, which are principally, if not solely, used in vivo as immunological agents for therapeutic or prophylactic purposes. *Blank* v. *United States*, *supra*, cited.

Court No. 68/54415-21133-68

Port of New York

[Judgment for defendant.]

(Decided April 3, 1974)

Sharretts, Paley, Carter & Blauvelt (*Eugene F. Blauvelt* and *Gail T. Cumins* of counsel) for the plaintiff.

Carla A. Hills, Assistant Attorney General (*James Caffentzis*, trial attorney), for the defendant.

NEWMAN, Judge: We are faced with a case, conceptually technical, concerning the dutiable status of certain rabbit antisera imported by plaintiff from West Germany in 1968. The merchandise was assessed with duty at the rate of 9 per centum ad valorem under the provision in item 799.00 of the Tariff Schedules of the United States (TSUS) for "Other" articles not provided for elsewhere in the tariff schedules. Plaintiff claims that the merchandise is free of duty under the provision in item 437.76, TSUS, for "Viruses, therapeutic serums, vaccines, toxins, antitoxins, and analogous biological products".

For the reasons stated below, the protest is overruled.

THE RECORD

Counsel for the parties orally stipulated at the trial that at the time of importing the antisera no license was issued or required pursuant to the Public Health Service Act of July 1, 1944, as amended, 42 U.S.C. § 262. See footnote 4.

Stephan E. Ritzmann, M.D., called as a witness on behalf of plaintiff, was Director of the Division of Experimental Pathology and Immunology, and Codirector of the Transplantation Immunology Laboratory at the University of Texas Medical Branch. Dr. Ritzmann

specializes and is an expert in the fields of hematological diseases, immunology, immunochemistry, transplantation and blood banking.

Dr. Ritzmann's testimony may be summarized as follows:

The antisera were produced by Behringwerke AG. in West Germany, and consist of a fraction of the blood of rabbits which has been sensitized to certain antigens. These antigens, proteins from the blood of normal adults and from the blood of patients with certain types of cancer referred to as monoclonal gammopathies, were injected into the blood stream of rabbits. After a latent period, specimens of the rabbits' blood were drawn and assayed for potency of antibodies directed against the antigens, the proteins previously injected. If the potency and specificity of the antibodies met certain requirements, large amounts of blood were drawn from the rabbits and the serum component was separated therefrom.

Dr. Ritzmann described the nature of serum (R. 21):

> Drawing whole blood and letting it stand in a test tube for, let's say, two hours, the blood will separate into two components, one on the bottom of the test tube consisting of mainly red cells and the second column above consisting of clear to slightly yellowish fluid referred to as serum, containing numerous serum proteins, enzymes, et cetera.

After separating the serum from the rabbits' blood cells, the serum was subjected to testing against the original antigen or protein injected into the rabbits to determine whether or not the serum reacted with it. If the serum reacted with the original antigen injected into the rabbits, a visible precipitin line indicated an antibody-antigen reaction. The strength of this reaction was determined by using one of several methods. The specificity of the antibodies was then tested to ascertain whether or not they were reacting only with the particular antigen or protein injected into the rabbits. Subsequently, additional specimens of blood were drawn from the rabbits and were tested in the same manner.

In order to provide large batches of antisera with a known antibody potency and specificity, small quantities of antisera were pooled and blended, and ultimately the antisera were aliquoted into vials containing from 0.5 to 50 milliliter volumes. This was the condition in which plaintiff imported the antisera.

The antisera are used in a technique called immunoelectrophoresis (IEP), which "is a method of choice for the diagnosis and differential diagnosis of the Monoclonal Gammopathies" (R. 24). Such differential diagnosis is necessary because "patients with one particular type of this disease, referred to as IgG, Monoclonal Gammapathies, usually respond to a particular group of drugs, chemotherapeutic drugs;

whereas, those patients with IgM, Monoclonal Gammopathies, respond better to a different type of chemotherapeutic drugs" (R. 16).

In a patient with monoclonal gammopathies, certain blood cells undergo a malignant or cancerous proliferation, and there is a production of antibody proteins in abnormal amounts in the patient's blood.

When a blood sample is received for an IEP analysis the serum is first separated from the red cells. The serum is then added to an agarose coated plastic film and electrophoresized, that is to say, it is subjected to an electrical current which results in the migration of the various proteins contained in the serum into various positions. Thereafter, a specific antiserum is added to a trough which is parallel to the electrophoretically separated serum proteins. Then, both the electrophoretically separated serum proteins and the antiserum diffuse in the agarose medium; and where they meet an antigen-antibody reaction occurs, reflected by the formation of precipitin lines. Various precipitin patterns are evidence of the presence of abnormal serum proteins, thus permitting a differential diagnosis of the various monoclonal gammopathies.

The results of the IEP test are reported by Dr. Ritzmann to the patient's physician. Thereupon, some physicians call Dr. Ritzmann, requesting recommendations concerning further diagnostic or therapeutic steps, and he answers their inquiries. In one instance where Dr. Ritzmann made a diagnosis of monoclonal gammopathies, it was decided that the patient required two forms of treatment: chemotherapy and mechanical removal of the abnormal proteins.

The following definition of "antitoxin" in *Dorland's Illustrated Medical Dictionary* (edition not identified) was read to Dr. Ritzmann: "Antibody to the toxin of a microorganism, usually the bacterial exotoxins, that combines specifically with the toxin, in vivo and in vitro, with neutralization of toxicity". In connection with this definition the following question and answer appear in the record (R. 35):

> Q. And, in your opinion, does the imported serum or sera fall within that Dorland's Dictionary definition of "antitoxin"?—A. In a wider sense, yes, in that it is also reacting with an antigen and a toxin is nothing but a specific type of antigen against which the antibody reacts.

Additionally, the following definition of "antitoxin" in *Webster's Seventh New Collegiate Dictionary* (1967) was read to Dr. Ritzmann: "An antibody formed in the body as the result of the introduction of a toxin and capable of neutralizing the specific toxin which stimulated its production, and produced commercially in animals by injection of a toxin or toxoid, as of human disease, with the resulting serum being

used to counteract the toxin in other individuals". Dr. Ritzmann agreed with this definition, "provided that it is recognized that the definition in clinical settings is usually wider than given here" (R. 35–36).

On cross-examination, Dr. Ritzmann testified that in 1968 large amounts of the antisera were used in research "in order to gain experience" (R. 55).

Defendant introduced no evidence.

In summary, the record clearly establishes the following pertinent facts: the antisera were produced by injecting antigens in the form of certain proteins from human blood into the blood stream of rabbits, and if the requisite antibody reaction occured in the rabbits' blood, such blood was drawn from the rabbits and processed into the antisera. The antisera's sole commercial use was as a diagnostic reagent (in vitro) for the differential diagnosis of monoclonal gammopathies thereby permitting the patient's physician to use the most effective chemotherapeutic drugs to treat the disease.

Plaintiff's Contentions

1. The antisera are "therapeutic serums"; and
2. The antisera are "antitoxins".
3. Alternatively, the antisera are "analogous biological products".

Therapeutic Serums

1.

Plaintiff argues "that the imported diagnostic sera are, in fact, therapeutic sera, in that they are excusively used in the diagnosis of human blood diseases and that diagnosis is essential to medical treatment of the disease".

Defendant contends "that the provision for therapeutic serums in item 437.76, TSUS, does not encompass the serum at bar, inasmuch as the latter is not used to prevent, cure, alleviate or remedy any disease or injury".

Since there is no dispute that the antisera are "serums", we shall initially consider the meaning of the term "therapeutic". Since common meaning is involved, the court may as an aid consult dictionaries, lexicons and other written authorities. *Sandoz Chemical Works, Inc.* v. *United States*, 43 CCPA 152, C.A.D. 623 (1956).

The term "therapeutic" is defined in *Webster's Third New International Dictionary* (1966) and *Webster's New International Dictionary, Second Edition* (1950), respectively, as follows:

> therapeutic * * * of or relating to the treatment of disease or disorders by remedial agents or methods: CURATIVE, MEDICINAL <~diet> <~dose> * * * therapeutic * * * Of or pertaining to the healing art; concerned with remedies for disease; curative. Cf. PROPHYLACTIC.

Funk & Wagnalls New Standard Dictionary of the English Language (1952) gives the following definition:

> therapeutic, * * * *a.* Med. 1. Having healing qualities; curative; alleviative.

The *Modern Science Dictionary* (1959) provides the following definition:

> therapeutic. Healing, remedial, or curative.

The following definition of "therapeutic" in *A New English Dictionary on Historical Principles*, Vol. IX, part II (1919), p. 280, significantly makes a distinction in medical treatment between that which is therapeutic and that which is diagnostic:

> Therapeutic * * *
>
> 1. That branch of medicine which is concerned with the remedial treatment of disease; the art of healing. * * * 1625 Hart *Anat. Ur.* 1. ii. 19 Who did likewise deuide [divide] Physicke [medical treatment] . . into two parts, to wit, that which we commonly call Therapeuticke [therapeutic] . .: and . . that part which we call Diagnosticke [diagnostic.] [1]
>
> 2.a. A curative agent.

Some further light on the meaning of "therapeutic" may be obtained from *United States* v. *23 7/12 Dozen Bottles, 35-Cent Size, etc.*, 44 F. 2d 831, 833–34 (D.C. Conn. 1930) wherein the court considered the meaning of the term "therapeutic" as used in a statute relating to misbranding of drug preparations (Food and Drug Act of June 30, 1906, § 8, 34 Stat. 768, amended by the Act of August 23, 1912, 37 Stat. 416). The court observed:

> * * * Therapeutic to the medical world means to heal; to make well; to restore to health. It is that branch of medicine dealing with the proper use of the right medicines in the treatment of diseases. The medical student studies "Therapeutics" for the purpose of learning about different medicines to prescribe for the many ills to which the flesh is heir, in order to assist nature to make a sick patient well. The ordinary definitions found in the dictionaries are as follows: "Having healing qualities; curative; alleviative; a medicine efficacious in curing or alleviating disease." Webster defines therapeutics as "that part of medical

[1] "1625 Hart *Anat. Ur.* 1. ii. 13: Diagnosticke whose most common scope is to discerne . . . the sick and infirme from the whole". *A New English Dictionary on Historical Principles*, Vol. III, part I (1897), p. 307.

science which treats of the discovery and application of remedies for diseases." * * *

2.

As may be noted, in its abstract sense and unrelated to serums, the term "therapeutic" is susceptible of more than one meaning. On the one hand, the term refers to the *remedial* treatment of disease, or to a substance which is healing, curative, or alleviative; on the other hand, the term can mean: "of or pertaining to the healing art", an obviously broader definition that could include the diagnosis of disease. Cf. *Sandoz Chemical Works, Inc., supra.* Under these circumstances, the meaning of "therapeutic" intended by Congress may be gleaned more accurately by ascertaining such meaning, not in the abstract sense, but rather in relation to the term "serum" which is modified by the adjective "therapeutic". Accordingly, lexicographic and other materials pertaining to serums have been consulted. The following excerpts from several authorities are deemed indicative of the appropriate meaning to be ascribed to the term "therapeutic" when used to modify the term "serums", as in item 437.76.

Van Nostrand's Scientific Encyclopedia (4th ed. 1968) describes serum as follows (p. 1605):

> SERUM. The clear, slightly yellow liquid which is freed when blood is allowed to clot. The blood cells and fibrin are removed and the remaining fluid is serum. * * *
>
> The antibodies, which are important in protecting against disease, are contained in the globulin fraction of the serum. Various types of sera are therefore collected from individuals who have had a given disease (convalescent sera) to use prophylactically or *therapeutically* in other individuals exposed to, or ill with, the same disease. Effective antisera are also obtained by immunizing animals such as horses and rabbits, bleeding them, and preserving the serum. *Antitoxic* sera are obtained for use against disease caused by toxin-producing bacteria such as diptheria, tetanus, botulism, scarlet fever, etc. *Anti-bacterial* sera are used against pneumonia, meningitis, anthrax and other bacterial diseases. A *polyvalent* serum is one containing antibodies to several usually related organisms or toxins. [Emphasis added in part.]

The encyclopedia also states (p. 1605) that serum reactions "may follow the administration of *therapeutic* or prophylactic *sera* (see Immunization) to persons who have a natural or acquired sensitivity to foreign protein" (emphasis added). Under the subject "IMMUNIZATION", the following appears:

> Active immunity provides long-term protection; where immediate short-term protection is required, this may be provided by passive immunity, the transfer to the susceptible person of the serum of (usually) an animal who has previously been hyper-

immunized against the infection concerned. Such a serum is sufficiently rich in antibodies to tide the recipient over the period immediately following exposure to infection, and even if complete prevention is not secured, the attack which develops may be greatly reduced in severity. Such prophylactic sera are commonly employed against diphtheria, tetanus, and gas gangrene. *Similar sera were formerly much employed for therapeutic purposes, but their use has declined with the rise of chemotherapy.* [Emphasis added.]

The Dispensatory of the United States of America (25th ed. 1955), pp. 1841–44, under the subject of "Serums and Serum Derivatives", states:

Antibodies are produced by injecting various animals, usually horses (cattle, goats and rabbits are also used commercially), with the antigen which causes the animal to produce specific antibodies. Inasmuch as the blood serum of the treated animal serves as the usual vehicle by which the antibodies are transferred, the method is commonly spoken of as *serum therapy.* * * * [Emphasis in original.]

* * * * * * *

ANTIBACTERIAL SERUMS are the serums obtained from the blood of animals which have been immunized against particular bacteria and contain antibodies antagonistic for the latter. These serums are more complex in composition and generally less certain in their *therapeutic action* than the antitoxins. * * * [Emphasis added.]

* * * * * * *

* * * Due to the lack of definite standards and the uncertainty of any beneficial effects, the antibacterial serums are not employed so extensively as *therapeutic agents as are the antitoxins, though many therapeutic serums have been marketed.* [Emphasis added.]

* * * * * * *

Antimeningococcic Serum, * * *.

* * * * * * *

* * * Since sulfadiazine, sulfamerazine and penicillin have become available, the use of antimeningococcal serum has almost ceased. Both sulfonamides and penicillin give better *therapeutic results* than antimeningococcic serum and mortality rates of less than 8 per cent are reported. The use of these chemotherapeutic and antibiotic agents is so simple and effective that *now serum is largely reserved for the critically ill patient who is in need of all possible therapeutic assistance. In these cases, antimeningococcic serum is administered as an adjunct to sulfonamide or penicillin therapy.* * * * [Emphasis added.]

Blakiston's New Gould Medical Dictionary (2d ed. 1956), p. 1088, in defining the term "serum" notes:

* * * The fact that the serums of immunized animals and of man contain antibodies, etc., has resulted in extensive use of serums for diagnosis, prophylaxis, and *therapy.* [Emphasis added.]

Stedman's Medical Dictionary (20th ed. 1961), p. 1349, defines "serotherapy":

> serotherapy. * * * 1. Treatment of an infectious disease by the injection of an antitoxin or specific serum. * * *

Hence, the foregoing authorities describing serums strongly indicate that "therapeutic serums" are those serums containing antibodies which are used in vivo as immunological agents for the conferring of passive immunity to certain diseases. Moreover, in determining the scope of the provision for "therapeutic serums" in item 437.76, I deem it significant that the other biological products provided for *eo nomine* in item 437.76, TSUS (viruses, vaccines, toxins, and antitoxins), are similarly immunological agents used in vivo. See *Summary of Tariff Information* (1929), Schedule 15, pp. 2292–94.

3.

As an aid to interpreting item 437.76, TSUS, defendant cites the *Tariff Classification Study Explanatory and Background Materials*, November 15, 1960,[2] Schedule 4, part 3, p. 86, which states:

> * * * Also, the provisions of items 437.44 through 437.52, as published, relating to biologicals provided for in paragraph 1610 have been consolidated and enlarged in scope in final proposed item 437.76 to do away with certain artificial distinctions now involved and thereby make a more coherent group of related articles which *substantially correspond with the scope of the licensing requirements of the Public Health Service and the Department of Agriculture applicable to the importation of certain biological products.* Human blood and fractions there of [sic] and anatomical parts of the human body have been specifically added to the new provision. The rate changes involved in item 437.76 are unimportant. [Emphasis added.]

The licensing requirements of the Public Health Service mentioned in the above explanatory notes originated with the Act of July 1, 1902, ch. 1378, § 1, 32 Stat. 728, prohibiting the importation or sale in interstate commerce of any "virus, *therapeutic serum*, toxin, antitoxin or analogous product *applicable to the prevention and cure of diseases of man*" (emphasis added), unless the producer of such products was licensed by the Secretary of the Treasury.

The purpose and intended scope of the 1902 statute are reflected by the following comment in H.R. Rep. No. 2713, 57th Cong., 1st Sess. (1902), p. 2 and S. Rep. No. 1980, 57th Cong., 1st Sess. (1902), p. 2:

> This bill seeks, as indicated by its title, to regulate the manufacture and sale of certain substances of animal origin which,

[2] The *Tariff Classification Study*, published by the United States Tariff Commission pursuant to Congressional delegation (Customs Simplification Act of 1954, Public Law 83–768, 68 Stat. 1136), is regarded by the courts as a source of legislative history of the TSUS. See *Rifkin Textiles Corp.* v. *United States*, 54 CCPA 138, C.A.D. 925 (1967).

except vaccine virus, have but recently come into general use for the prevention and cure of disease. The purity of these substances is of far more importance than is the purity of ordinary drugs because *the former are ordinarily introduced into the circulation directly* while the latter are introduced through the digestive tract. [Emphasis added.]

In 1944, Congress reenacted the provisions of the 1902 act, with some modifications, as part of the codification of the laws pertaining to the Public Health Service. Act of July 1, 1944, ch. 373, § 351(a), 58 Stat. 702.[3] The present statute appears at 42 U.S.C. § 262(a),[4] and as in the 1902 act, one of the biological products covered is "therapeutic serum".

In *Blank* v. *United States*, 400 F. 2d 302 (CA 5, 1968), one of the questions presented under 42 U.S.C. § 262 was "whether as a matter of statutory construction citrated whole blood and packed red blood cells are analogous to a therapeutic serum". Concerning that issue, the Court of Appeals observed (at p. 304):

> The products enumerated in the 1902 statute are immunological agents. "Serum" is "1) the clear portion of any animal liquid separated from its more solid elements; especially the clear liquid which separates in the clotting of blood from the clot and the corpuscles, 2) Blood serum from animals that have been inoculated with bacteria or their toxins." *Serum's principal, if not sole, therapeutic function is as a passive immunological agent; that is, therapeutic serum contains antitoxic or antibacterial antibodies which neutralize or counteract toxins or bacteria. Serum is administered by injection* and is used in the prevention, treatment and cure of such diseases as mumps, pertussis, diphtheria, scarlet fever, pneumonia and meningitis. *Toxins, antitoxins and viruses also are immunological agents.* Toxins (toxoids) and viruses are active in that they generate the production of antibodies; anti-

[3] From the Congressional debates on the 1944 revision, it is apparent that no substantive change (other than the addition of arsphenamines and derivatives) in the 1902 act was intended. See *Blank* v. *United States*, 400 F. 2d 302 (CA 5, 1968).

[4] 42 U.S.C. § 262(a) (1964 ed.) provides, in part:

§ 262. Regulation of biological products.

(a) Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales.

No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; * * *

> toxins are passive, containing preformed antibodies. [Footnote references omitted.] [Emphasis added.]

Inasmuch as neither citrated whole blood nor packed red blood cells are medically employed as immunological agents, the Court of Appeals held that neither product was a "therapeutic serum" or analogous thereto. Thus, as construed by the Court of Appeals in *Blank*, a "therapeutic serum" within the purview of 42 U.S.C. § 262 is a serum containing antitoxic or antibacterial antibodies which neutralize or counteract toxins or bacteria, and is administered by injection, for the conferring of passive immunity to various infectious diseases. This construction of § 262 in *Blank* is highly significant in the present case inasmuch as Congress intended the scope of item 437.76 to "substantially correspond with the scope of the licensing requirements of the Public Health Service".[5] See also 19 CFR § 12.21 (1968).[6]

Furthermore, in determining whether the imported antisera fall within the purview of item 437.76, it is a relevant consideration that at the time of importation of the antisera no license was issued or required by the Secretary of Health, Education, and Welfare pursuant to 42 U.S.C. § 262, as stipulated by the parties.

4.

Both this court and our appellate court have frequently resorted to the Tariff Commission Summaries of Tariff Information for the purpose of ascertaining Congressional intent. See e.g. *Sandoz Chemical Works, Inc.*, *supra*, at pp. 156–58, where the term "medicinal" was held ambiguous, therefore justifying resort to extrinsic aids.

In the *Summaries of Tariff Information*, Vol. 16 (1950), part 1, p. 116, the following comment appears concerning paragraph 1610 of the Tariff Act of 1930:[7]

> This summary covers: (1) Antitoxins, (2) vaccines, (3) viruses, (4) serums, and (5) bacterins, used for therapeutic purposes. These five kinds of therapeutic products account for most of the biological medicinals produced for human and veterinary use.[1]

Footnote 1 states: "There are certain other biological products, such as toxins, antigens, *diagnostic agents*, and blood fractions, which may

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[5] *Tariff Classification Study Explanatory and Background Materials*, November 15, 1960, Schedule 4, part 3, p. 86.

[6] 19 CFR § 12.21 (1968) provides: "The bringing into the United States for sale, barter, or exchange of any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man is prohibited unless such virus, serum, toxin, antitoxin, or product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license for such propagation".

[7] Paragraph 1610, Tariff Act of 1930 read: "Antitoxins, vaccines, viruses, serums, and bacterins, used for therapeutic purposes". Similar provisions appeared in paragraph 1510, Tariff Act of 1922 and paragraph 400, Tariff Act of 1913.

or may not be included herein depending on whether or not they are in the form of or are incorporated in vaccines or *serums.* * * *" (Emphasis added.)

However, the following specific definition of a "therapeutic serum" from the regulations of the Federal Security Agency is quoted by the Tariff Commission (p. 116):

> "A therapeutic serum is the product obtained from the blood of an animal by removing the clot or clot components and the blood cells *and intended for administration by a route other than ingestion.*" Common examples are antipertussis (anti-whooping cough) serum and anti-hog-cholera serum. [Emphasis added.]

Concerning the above-mentioned regulations of the Federal Security Agency,[8] the Tariff Commission pointed out (p. 116):

> Under the provisions of the Public Health Service Act, approved July 1, 1944, the sale, importation, or possession of any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of *man* is forbidden unless the product is licensed by the Federal Security Administrator. * * * [Emphasis in original.]

In the *Summary of Tariff Information* (1929), Schedule 15, pp. 2192–94, the following comments appear concerning paragraph 1510 of the Tariff Act of 1922:

> Description and uses.—Antitoxins, vaccine virus, seriums, etc., are used in the prevention, diognosis [sic], and treatment of disease in man and animals. The use of an individual vaccine or antitoxin is usually limited to a particular disease. The sale and propagation of these products are controlled by the Public Health Service under the act of July 1, 1902, whereby the importation, exportation, or interstate sale of such products, designed for human use, is forbidden unless the manufacturer be licensed by the Secretary of the Treasury.
>
> * * * * * * *
>
> Production.—* * * A description of the principal biologicals and of the way in which they are produced and used follow:
>
> * * * * * * *
>
> 4. Serums.—*There are three general classes of serums: Normal, antibacterial, and antitoxic serums.* The antitoxic serums or antitoxins are the most important. They are all derived almost entirely from the horse, by immunization with cultures of various types of bacteria. Bacteria are used which produce no demonstrable toxin against the specific toxins of such a disease as produce them. (a) Normal serums are used to some extent in hemmorrlogic

[8] The functions of the Federal Security Administrator were transferred to the Secretary of Health, Education, and Welfare; and the office of Federal Security Administrator was abolished by §§ 5, 8 of Reorg. Plan No. 1 of 1953. See transfer of functions note to 42 USCS§ 202.

conditions. (b) Antibacterial serums are employed against anthrax, meningitis, pneumonia, streptococcus infections, etc. (c) Antitoxic serums or antitoxins are of limited number but of dominant therapeutic importance. Use of antitoxins is held by Public Health authorities to be largely responsible for greatly decreased incidence and fatalities from diphtheria, tetanus, and scarlet fever in recent years. Mixed toxin-antitoxin is largely used in diphtheria immunization. An antitoxin against rattlesnake bite has also been developed. [Emphasis added.]

* * * * * * *

As may be noted above, no diagnostic *serums* were called to the attention of Congress in the 1929 *Summary* under paragraph 1510, and the only serums described are: normal, antibacterial and antitoxic.

True, in the 1950 *Summaries*, the Tariff Commission indicated in a footnote under paragraph 1610 that diagnostic agents were included in that paragraph if they were in the form of or incorporated in serums. More pertinent, however, the definition of "therapeutic serum" quoted by the Tariff Commission in its comment included only those serums "intended for administration by a route other than ingestion", viz., parenterally. The imported in vitro diagnostic sera were, of course, not intended for administration to a patient parenterally or otherwise.

Defendant has called attention to the *Summaries of Trade and Tariff Information*, Schedule 4, Vol. 7 (1971), p. 117,[9] wherein the Tariff Commission stated with reference to item 437.76, TSUS:

> The biological products covered by this summary and included in item 437.76 are: viruses, therapeutic serums, vaccines, toxins, toxoids, antitoxins, and analagous products (such as allergenic extracts); human blood, plasms, and other fractions of blood; and anatomical parts of the human body prepared for diagnostic or therapeutic purposes. Also covered by this summary is the protein fibrin. *Not included are diagnostic (as contrasted with therapeutic) serums derived from the blood of rabbits, which are provided for under item 799.00 pursuant to Treasury Decision 67–113(2).* [Emphasis added.]
>
> The products included here are used in medicine and surgery for such purposes as immunization, diagnosis, and therapeutic treatment of animals and humans. Immunizing agents, imported as well as those produced domestically, are important aids in controlling infectious disease in the United States.

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[9] The *Summaries of Trade and Tariff Information* have been referred to as an aid in determining the scope of tariff provisions. See e.g. *American Bristle & Hair Drawing Co., Keer Maurer & Co.* v. *United States*, 59 CCPA 104, C.A.D. 1048, 458 F. 2d 524 (1972); *Tanross Supply Co., Inc.* v. *United States*, 58 CCPA 26, 31, C.A.D. 1000, 433 F. 2d 1332 (1970). See also *Lyons Export & Import, Inc.* v. *United States*, 59 CCPA 142, 144, C.A.D. 1056, 461 F. 2d 830 (1972).

5.

While the above comments of the Tariff Commission are not dispositive in this case, they appear to be consistent with the Congressional intent manifested by the express language of item 437.76. "It is * * * well settled that the master rule to be used in the construction of tariff statutes is to ascertain the legislative intent". *Sandoz Chemical Works, Inc., supra.*

Significantly, in item 437.76 the word "diagnostic" was not used with reference to serums, but in the same item number Congress provided for:

> * * * Human skin and bone grafts, and other anatomical parts of the human body prepared for *diagnostic or therapeutic* purposes. [Emphasis added.]

The fact that Congress deemed it necessary to employ the term "diagnostic" as well as the term "therapeutic" with reference to anatomical parts indicates that Congress understood the two terms to mean something different. Moreover, when Congress intended to include in item 437.76 articles used for diagnostic purposes, it left no doubt concerning its intent.[10] Under all the circumstances, I conclude that the term "therapeutic serums" as used in item 437.76, TSUS, were not intended to embrace diagnostic serums, such as those involved in this case.

6.

In reaching the foregoing conclusion I have carefully considered the cases of *Air Express International Agency, Inc., a/c Hyland Laboratories* v. *United States*, 52 Cust. Ct. 254, Abs. 68288 (1964), and *Sandoz Chemical Works, Inc.* v. *United States*, *supra*, relied upon by plaintiff.

In *Air Express*, the court held that blood grouping serum used by laboratories, hospitals, blood banks, and others as a reagent for determining the compatibility of blood for transfusions was a serum "used for therapeutic purposes" within the purview of paragraph 1610 of the Tariff Act of 1930.

In *Sandoz Chemical Works, Inc.*, the appellate court held that a drug chiefly used for diagnostic purposes was a "medicinal" under paragraph 28(a) of the Tariff Act of 1930. It should be pointed out that the term "medicinal" is given as a synonym for "therapeutic" in some lexicographic authorities. See e.g. *Webster's Third New International Dictionary*, *supra.*

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[10] Along the same line, it is instructive to note paragraph 353 of the Tariff Act of 1930, as modified by T.D. 54108, which provided for: "Electrical therapeutic (including diagnostic) apparatus, * * *". See *Westinghouse Electric International Co.* v. *United States*, 28 Cust. Ct. 209, 220–21, C.D. 1411 (1952).

In my opinion, neither of the above-cited cases is determinative of the interpretation of the term "therapeutic" as used in item 437.76 since the tariff paragraphs construed in those cases were worded very differently from item 437.76, TSUS.[11] Stated differently, in neither *Air Express* nor *Sandoz Chemical Works, Inc.*, were the courts interpreting the term "therapeutic serums" in a tariff provision like item 437.76. It is emphasized that in item 437.76 the terms "therapeutic" and "diagnostic" were used with reference to anatomical parts, while only the term "therapeutic" was used with reference to serums. As indicated above, by employing only the term "therapeutic" with reference to serums Congress clearly manifested an intent that diagnostic serums were not to be included as well.

7.

Additionally, I have considered plaintiff's argument that Congress presumably knew of and thus approved the holding of the Customs Court in the *Air Express* case inasmuch as no amendments to item 437.76 were recommended when H.R. 7969 (which became the Technical Amendments Act of 1965, P.L. 89–241, 79 Stat. 933) was being considered in Congress. However, even assuming *arguendo* that under these circumstances there may be legislative ratification of judicial construction, it must be recognized that item 437.76 was not construed in *Air Express*.[12] There, the term "therapeutic" was construed under paragraph 1610 of the Tariff Act of 1930, which it is again emphasized is worded somewhat differently than item 437.76 of the tariff schedules. Hence, Congress cannot be said to have approved the *Air Express* holding as the intended interpretation of item 437.76.

ANTITOXINS

We now reach plaintiff's second claim, namely, that the antisera fall within the provision for "antitoxins" in item 437.76, TSUS.

As noted in *Blank*, *supra*, 400 F. 2d at p. 304, antitoxins are immunological agents which contain performed antibodies, and hence confer passive immunity to infectious diseases. In that connection, the following description of "antibodies" and "antigens" in *The Dispensatory of the United States of America* (25th ed. 1955), pp. 1841–42, is illuminating:

[11] The changes in the language of paragraph 1610, Tariff Act of 1930 were basically as follows: The requirement in paragraph 1610 that *all* of the biologicals named be "used for therapeutic purposes" was eliminated; "therapeutic serums" replaced "serums"; "bacterins" were eliminated; "analogous biological products" and "Human skin and bone grafts, and other anatomical parts of the human body prepared for diagnostic or therapeutic purposes" were entirely new provisions.

[12] In fact, the present case is the first involving the scope of the term "therapeutic serums" as used in item 437.76, TSUS.

> * * * Antibodies are specific protective substances produced by the tissue cells of the host in reaction against an antigen. The term antigen designates any substance—such as infecting animal parasites, bacteria, or other foreign protein—capable of causing the development of specific antibodies in the circulation of animals to which it is administered parenterally. The number of substances which may act as antigens is very large; practically any foreign protein may serve as an antigen. The kinds of specific antibodies produced vary. *Some—as the antitoxins—have the power of neutralizing the soluble toxins of bacteria;* * * *. [Emphasis added.]

In Dorland, *The American Illustrated Medical Dictionary* (21st ed. 1947), antitoxin is described as follows (p. 123):

> antitoxin * * *. A substance found in the blood serum and in other body fluids which is *specifically antagonistic to some particular toxin.* Antitoxins are sometimes found in small amount normally, but they may be greatly increased by injecting the corresponding toxin. The antitoxins for therapeutic use are prepared by injecting a horse with gradually increasing doses of the toxin of a disease; thus the natural immunity of the animal is increased by the formation of antitoxin of the disease. *The antitoxin-laden serum withdrawn from the animal is used by injection to increase the resistance of a person to the disease in question.* [Emphasis added.]

A number of different kinds of specific antitoxins are described in Dorland's dictionary, but two well-known types illustrate typical antitoxins (p. 123–24):

> diphtheria a., the antitoxin which will suppress the harmful effect of diphtheria toxin. It is found normally in small amounts in various animals and in man; in larger amounts in persons who have recovered from an attack of diphtheria; and can be produced in enormous amount and potency for use as a therapeutic agent by injecting animals (usually horses) with diphtheria toxin.
>
> tetanus a., the antitoxin which will suppress the harmful effect of tetanus toxin. It is produced by injecting animals (usually horses) with tetanus toxin. It is used as a prophylactic and also as a therapeutic agent.

Van Nostrand's Scientific Encyclopedia, supra, at page 1605, states:

> * * * Effective antisera are also obtained by immunizing animals such as horses and rabbits, bleeding them, and preserving the serum. *Antitoxic* sera are obtained for use against *disease caused by toxin-producing bacteria* such as diphtheria, tetanus, botulism, scarlet fever, etc.* * * [Emphasis added in part.]

Webster's Third New International Dictionary (1966) defines "antitoxin" as follows:

> antitoxin * * *: an antibody formed in the body as a result of the introduction of a toxin and capable of neutralizing the specific toxin that stimulated its production, being produced for medical purposes by injection of animals (as horses) with gradually increased doses of *a toxin or toxoid* (as of diphtheria, tetanus, or botulism), *the resulting serum being used to counteract the same toxin in other individuals* * * * [Emphasis added.]

Encyclopaedia Britannica, Vol. 2 (1969), p. 92, states:

> * * * Antitoxin, like other antibodies, is usually associated with the gamma globulin fraction of serum protein and is produced in response to the antigenic stimulus provided by the inoculation of *toxin or toxoid*. [Emphasis added.]

From the foregoing authorities it appears that an antitoxin is produced in an animal by the injection of an antigenic stimulus *in the form of a toxin or toxoid*, and is *used in vivo to inoculate individuals to neutralize or counteract the specific type of toxin injected into the animal.*

Plainly, then, the imported diagnostic antisera do not fall within the foregoing concept of an "antitoxin". The antigens with which the rabbits were inoculated to produce the antisera were not in the form of a *toxin or toxoid*, and consequently the antibodies produced in the animal's blood were not antitoxic in nature. Moreover, the diagnostic antisera were not used in vivo to neutralize or counteract a *toxin.*

Dr. Ritzmann cautiously hedged by stating that an antitoxin "in a wider sense" includes any antibody response towards any antigen (R. 35). But such broad application of the term is entirely without support; and in fact is contrary to all the lexicographic and other authorities consulted by the court. Indeed, in their brief, counsel for plaintiff were unable to quote or cite a single dictionary definition or other lexicographic authority which supports Dr. Ritzmann's broad concept of an antitoxin! Therefore, his concept of an antitoxin, which is merely advisory, is rejected.

Finally, plaintiff's reliance upon the doctrine in customs jurisprudence that an *eo nomine* designation of an article includes all forms of the article is misplaced since the imported antisera are not a form of antitoxin.

Analogous Biological Products

We now turn to plaintiff's alternative contention that the antisera are "analogous biological products" within the purview of item 437.76, TSUS. Specifically, plaintiff contends that the antisera are analogous to therapeutic serums and antitoxins.

The predicate of the asserted analogy is that the antisera are produced by animals with a specific antigen and are used as an aid to

physicians in the "treatment" of disease. I have concluded that the antisera are analogous neither to therapeutic serums nor antitoxins.

The antisera do not perform the function of conferring immunity to disease or resistance to allergens.[13] Additionally, the imported antisera are not intended for parenteral administration as are therapeutic serums and antitoxins.[14] The antisera are medically employed as in vitro diagnostic aids, rather than in vivo, for therapeutic or prophylactic purposes as are therapeutic serums and antitoxins, respectively.

The fact that the antisera were produced from the blood of animals (rabbits) inoculated with certain antigens (which produced antibodies) is insufficient to constitute in vitro diagnostic aids for cancer as analogous to therapeutic serums and antitoxins, which are principally, if not solely, used in vivo as immunological agents for therapeutic or prophylactic purposes. In *Blank* v. *United States*, *supra*, the Court of Appeals pointed out that as neither citrated whole blood nor packed red blood cells were medically employed for immunological purposes, they were not analogous to therapeutic serums.

Conclusion

For the reasons stated, the protest is overruled, and judgment will be entered for the defendant.

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[13] The *Summary of Tariff Information* (1929), Schedule 15, p. 2194 states: "Analogous biological products of recent development include a large variety of pollen extracts, animal epidermalextracts, protein extracts, etc., used in the treatment of hay fever and similar diseases, which are caused by unusual susceptibility to proteins of plant pollens, animals, foods, etc."

[14] "Injection is a meaningful element of analogy but its impact is not great". *Blank* v. *United States*, 400 F. 2d 302, 305 (CA 5, 1968).

Decisions of the United States Customs Court

Custom Rules Decision

(C.R.D. 74–4)

VALLEY HARDWARE SUPPLY, INC. *v.* UNITED STATES

Memorandum to Accompany Order

Court No. 63/9283

Port of Houston on Administration

[Motion denied.]

(Dated April 3, 1974)

Stein & Shostak (*Marjorie M. Shostak* of counsel) for the plaintiff.
Carla A. Hills, Assistant Attorney General (*Robert B. Silverman*, trial attorney), for the defendant.

RICHARDSON, Judge: This is a motion by the defendant to dismiss for lack of jurisdiction, and to refer the action to an appropriate customs officer for appropriate administrative action.

In a stipulation before the Third Division by and between counsel for the respective parties, they agreed, among other things:

> "4. That the Official Court papers contain a copy of a Notice of Appraisement on Customs Form 4301, allegedly issued by the Collector of Customs under Sec. 501 of the Tariff Act of 1930, but that said copy retained in the entry file does not contain a notation of the date of delivery thereof to the importer, consignee, his agent, or his attorney.
>
> "5. That no written Notice of Appraisement on Customs Form 4301 issued by the Collector of Customs under Sec. 501 of the Tariff Act of 1930 was ever delivered to or received by the importer of record, consignee, his agent, or his attorney.
>
> * * * * * * *
>
> "8. That the above-entitled protest was timely filed at the port of entry on November 19, 1962, claiming that the liquidation was

premature, illegal, null and void, because of the failure to receive legal Notice of Appraisement as required by Sec. 501 of the Tariff Act of 1930 and Sec. 17.6 of the Customs Regulations.

"9. That in the absence of Notice of Appraisement as required by Sec. 501, and pursuant to 28 USC Sec. 2636(D), the matter may be remanded to a single Judge, sitting in reappraisement, for determination of the value of the merchandise in the manner provided by law."

On June 23, 1969, the Third Division ruled in accordance with the plaintiff's claim that "the liquidation was premature, illegal, null and void, because of the failure to receive Legal Notice of Appraisement . . ." and, pursuant to the above stipulation and the statutory requirements of 28 U.S.C.A. 2636(d) the Third Division remanded the matter "to a single judge sitting in reappraisement, for determination of the value of the merchandise in the manner provided by law." (*Valley Hardware Supply, Inc.* v. *United States*, 62 Cust. Ct. 1110, Abs. P69/322 (1969).)

Under the applicable statute when a liquidation is held to be void because it is based upon an appraisement which is void in that notice of appraisement was not sent to the importer it is mandatory that the matter be remanded to a single judge to determine value.

The provisions of 28 U.S.C.A., 2636(d) are:

"If upon the hearing of a protest, the court declares an appraisement of merchandise made after the effective date of the Customs Administrative Act of 1938 to have been invalid or void, it *shall* remand the matter to a single judge who shall determine the proper dutiable value of such merchandise in the manner provided by this chapter. In such proceeding no presumption of correctness shall attach to the invoice or entered values." (Emphasis added.)

July 23, 1973, the plaintiff filed its complaint seeking a reappraisement by a single judge in accordance with the remand.

Following two extensions of time to file its answer, on February 1, 1974, the defendant, who by stipulation had asked that the matter be remanded to a single judge for reappraisement in 1969, filed this motion in which it contends that the court is without jurisdiction to determine value as the appraisement is incomplete and *not invalid or void*, and requests that the court return the action to the appropriate customs officer "for appropriate administrative action," citing *The New Home Sewing Machine Co.* v. *United States*, 62 Cust. Ct. 895, R.D. 11655 (1969), an appeal to reappraisement case in which the court also held that a liquidation was *void* where a notice had been sent erroneously to the plaintiff before appraisement. See also Judge Landis, speaking for the majority in *Pistorino & Co., Inc.* v. *United States*, 67 Cust. Ct. 245 at p. 251, C.D. 4281 (1971), where the court

pointed out that the appeal to reappraisement in the *New Home* case was taken *prior to appraisement* as "Customs prematurely, and prior to appraisement, had given the importer notice that the appraisement had already been made when in fact it had not", and restated that the liquidation in the said case was *void*. The Court of Customs and Patent Appeals did not pass upon the *New Home* case when it was before it collaterally in *National Silver Co.* v. *United States*, 59 CCPA 185, (see p. 190), C.A.D. 1064, 463 F.2d 1387 (1972). The authority cited in the *New Home* case for support of the procedure of sending a case back to the appraiser to mail a notice of appraisement on the theory of incompleteness of appraisement, *Alfred Dunhill of London, Inc.* v. *United States*, 22 Cust. Ct. 209, C.D. 1178 (1949), did hold "that the appraisement was incomplete [where notice had not reached the importer], and that a proper notice of appraisement should be sent to the plaintiff so that the appraisement may be completed and plaintiff be given an opportunity, if it so desires, to file an appeal for reappraisement." The Government advanced the same "incompleteness of appraisement" theory citing the *Alfred Dunhill of London, Inc.* case, three years later in 1952, in the case of *United States* v. *James H. Rhodes & Co.*, 40 CCPA 1, C.A.D. 488 (1952), before the Court of Customs and Patent Appeals. However, the theory was rejected and the court followed the mandatory requirements of the statute and held that where there has been a liquidation upon a void appraisement there should be a "day in court."

Also, the *New Home* case was *a reappraisement case*. The involved case being a *protest* matter in a remand to a single judge to find value status, at the time Public Law 91–271 became effective, October 1, 1970, it is deemed, under rule 14.9(b)(2), a trial which had been commenced prior to October 1970, and is governed by practices and procedures in effect prior to October 1, 1970. The plaintiff has not responded to the motion to dismiss, but the judge in Motion Part has no authority to set aside a remand order by a Division entered pursuant to the request of both parties in a stipulation which was in conformity with mandatory statutory procedure in protest matters as required by 28 U.S.C.A. 2636(d); and dismiss the case for "incompleteness of appraisement" and refer it to the appropriate customs officer for proper administrative action.

The defendant's motion to dismiss for lack of jurisdiction is denied.

Rehearing Motion Filed

MARCH 29, 1974

Avins Industrial Products Co. *v.* United States, Court No. 72-3-00709.—METAL PRODUCTS—WIRE.—C.D. 4503. Motion by plaintiff.

Judgment of the United States Customs Court in Appealed Case

APRIL 1, 1974

APPEAL 5523.—International Seaway Trading Corp. *v.* United States.—FOOTWEAR—OVER 50 PERCENT BY WEIGHT OF RUBBER OR PLASTICS—WITH SOLES OF MATERIAL OTHER THAN LEATHER, WITH UPPERS OF VEGETABLE FIBERS—TSUS.—C.D. 4375 reversed December 20, 1973. C.A.D. 1112.

Tariff Commission Notice

Investigations by the United States Tariff Commission

DEPARTMENT OF THE TREASURY, *April 18, 1974.*

The appended notice relating to investigations by the United States Tariff Commission is published for the information of Customs Officers and others concerned.

VERNON D. ACREE,
Commissioner of Customs.

[TEA-W-233]

WORKERS' PETITION FOR A DETERMINATION UNDER SECTION 301(c)(2) OF THE TRADE EXPANSION ACT OF 1962

Notice of investigation

On the basis of a petition filed under section 301(a)(2) of the Trade Expansioin Act of 1962, on behalf of the workers and former workers of the Capital Footwear Corp., Worcester, Massachusetts, the United States Tariff Commission, on April 9, 1974, instituted an investigation under section 301(c)(2) of the Act to determine whether, as a result in major part of concessions granted under trade agreements, articles like or directly competitive with footwear for men (of the types provided for in items 700.35 and 700.55 of the Tariff Schedules of the United States) produced by said firm are being imported into the United States in such increased quantities as to cause, or threaten to cause, the unemployment or underemployment of a significant number or proportion of the workers of such firm or an appropriate subdivision thereof.

The optional public hearing afforded by law has not been requested by the petitioners. Any other party showing a proper interest in the subject matter of the investigation may request a hearing, provided such request is filed within 10 days after the notice is published in the *Federal Register.*

The petition filed in this case is available for inspection at the Office of the Secretary, United States Tariff Commission, 8th and E Streets, N.W., Washington, D.C., and at the New York City office of the Tariff Commission located in Room 437 of the Customhouse.

By order of the Commission:

KENNETH R. MASON,
Secretary.

Issued April 9, 1974.

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